EXHIBIT 9

CAUSE NO. 2012-CI-18690

JENNIFER RAMIREZ F/K/A JENNIFER GALINDO,	§	IN THE DISTRICT COURT
Plaintiff,	§	
v.	§	438th JUDICIAL DISTRICT
CESAR REYES, JOHNSON & JOHNSON, AND ETHICON, INC.,	§	
Defendants.	§	BEXAR COUNTY, TEXAS

EXPERT REPORT OF MICHAEL THOMAS MARGOLIS, M.D.

I. BACKGROUND AND QUALIFICATIONS

My curriculum vitae, attached hereto as Exhibit "A", more fully reflects my training, background, and publications, including those for the past ten years. I graduated from the University of Kansas Medical School in Kansas City, Kansas in 1987. I am licensed to practice medicine in the states of Wisconsin and California, where I also hold a valid California fluoroscopy x-ray supervisor and operator certificate. I did my internship in internal medicine for one year followed by three years of obstetrics and gynecology residency training under the direction of the father of urinary incontinence surgery, Dr. Kermit Krantz, M.D. (co-founder of the MMK procedure which is predecessor to the Burch procedure (still considered the gold standard procedure for the treatment of urinary incontinence)). After completing my residency, I became one of only a handful of fellowship-trained pelvic surgeons in the country to complete the pelvic surgery fellowship at Emory University in Atlanta, Georgia where I trained under the world renowned John Hopkins surgeon, Dr. Clifford Wheeless.

I currently hold hospital privileges at Mills Peninsula Medical Center in Burlingame, California, Good Samaritan Hospital in San Jose, ValleyCare Hospital in Pleasanton, Seton Medical Center in Daly City, Sequoia Hospital in Redwood City, El Camino Hospital, O'Connor Hospital in San Jose, Community Hospital of the Monterey Peninsula in Monterey, and several surgery centers. I currently serve as Vice Chairman in the Department of Obstetrics and Gynecology at Peninsula Hospital in Burlingame, California.

I am Board Certified in Obstetrics and Gynecology by the American Board of Obstetrics and Gynecology. I recently took and passed the first subspecialty board certification exam in the subspecialty of Female Pelvic Medicine and Reconstructive Surgery, thus becoming a member of the first class of Board Certified Pelvic Surgeons in the country. I am a fellow in good standing of the American College of Obstetrics and Gynecology and the American College of Surgeons and I am a member of multiple societies including: the American Urogynecologic Society, the Society of Pelvic Reconstructive Surgeons, the Northern California Chapter of the American College of Surgeons and the Kermit E. Krantz Society.

I am a District VII delegate to the California Medical Association. I have served at various hospitals as a member of various medical executive committees including service as chairman of the OB/GYN department at Los Gatos Community Hospital, quality management committees at Northwestern University, Stanford Hospital, Peninsula Hospital, and several hospitals in Wisconsin. I have served as president of the Peninsula Gynecologic Society and the Shufelt Gynecologic Society in San Jose, California.

I have held faculty positions in the Department of Obstetrics and Gynecology at Emory University in Atlanta, Georgia, Northwestern University in Chicago, Illinois, and Stanford University in California, where I have also served as chief of the division of gynecology and founder and director of The Stanford Center for Pelvic Reconstructive Surgery and Urogynecology. I have held clinical faculty appointments in the Department of Obstetrics and Gynecology at Stanford University and the University of Wisconsin in Milwaukee where I received the teaching excellence award in 2009.

I have been and continue to be actively engaged in the education and training of medical students, resident physicians, fellows and faculty at numerous universities and I currently teach on a daily basis and hold a clinical faculty position in the Department of Obstetrics and Gynecology at the David Geffen School of Medicine at UCLA, the Department of Obstetrics and Gynecology at Mbarara University of Uganda (where I also hold the title of visiting lecturer), and I am currently gynecology rotation site director at Valley Medical Center, Department of Obstetrics and Gynecology residency program in San Jose California. I have performed animal testing on many novel surgical instruments and I have performed field testing in humans for Boston Scientific sling anchor instruments in the past.

I have published numerous peer-reviewed and non-peer-reviewed publications in the field of obstetrics and gynecology and have written several book chapters in the field as well. These publications including those in the past 10 years are listed in my CV (Exhibit A). I have lectured extensively throughout the US and abroad on numerous subjects involving sling and mesh complications and advanced pelvic surgery, including the treatment of prolapse and incontinence. I have presented original scientific peer reviewed articles at the Society of Gynecologic Surgeons and I have presented surgical videos at the American College of Obstetrics and Gynecologists annual meeting. I have served as reviewer of the Journal of Reproductive Medicine and the International Journal of Obstetrics and Gynecology.

Pursuant to a request by the FDA, on September 8, 2011, I testified at the FDA hearing for the Obstetrics and Gynecology Devices Panel in Gaithersburg, Maryland on the serious issue of complications of the transvaginal synthetic mesh placement. My address was based on my knowledge, experience, education, and training as a pelvic surgeon and on observations made during scores of salvage operations I have performed on women who have experienced mesh and sling complications since 1996. During my address, I made the analogy that extirpation of the vaginal mesh was akin to using a hammer and chisel and trying to remove the rebar from a sidewalk while leaving the cement otherwise intact and not damaging the water mains and power lines below. Since my FDA testimony and based upon my further experience with slings and mesh, I have found that it may even be more dramatic and challenging than that.

I am the medical director of Medlend Medical Missions to Developing Countries, a nonprofit organization that provides free surgical care to women in need around the globe. I have participated in 10 different surgical missions throughout Ghana, Peru, and Uganda. I am team leader of the yearly fistula mission to Uganda where I direct trainees from around the world in the repair of complex gynecologic injuries, often related to pelvic organ prolapse and incontinence.

I am in private practice of pelvic surgery and urogynecology in the Bay Area of California. I perform on average 10 major surgical procedures per week. I have performed over 15,000 surgical procedures in my professional career, including approximately 1,500 organic (non-synthetic) sling procedures. The majority (90%) of my patients are referred to me by other gynecologists for complications associated with prior gynecologic surgery, prolapse, incontinence, fistulas and polypropylene or other synthetic mesh and sling related injuries. Since 1996, I have removed over 200 mesh or sling systems in patients who have suffered numerous complications. Although when removing mesh, I do not always know what particular mesh was implanted. In the early years, as my expertise at explant surgery developed, in order to assist in the removal, I would gain access to the implant records and to learn which particular synthetic mesh was involved. In this regard, I would also review the applicable Instruction for Use (IFU). Frequently, the product has been one of the TVT products manufactured by J&J/Ethicon, Inc., including the TVT-O device at issue in this case.

Within the last 1 to 2 years, the number of patients with synthetic mesh or sling related complications presenting to me for definitive surgical treatment has increased dramatically. I now remove on average two sling or mesh systems per week and the number continues to rise. Patients are referred to me for sling and mesh complications from across the country. These patients include women with the TVT Obturator device.

In order to more fully understand how to deal with the complications of these synthetic mesh systems and to remove them as effectively as possible, I have personally observed numerous sling and mesh insertion procedures by colleagues of mine and through industry videos from a variety of manufacturers, including J&J/Ethicon, Inc. for their TVT products. As well, I have studied textbooks, publications, IFU's (including those from J&J/Ethicon, Inc. for the TVT-O's), surgical videos, cadaver dissections and countless operative reports as part of my study of sling and mesh surgeries. I have conferred with colleagues at conferences and in person throughout the country and abroad on synthetic mesh related complications.

Based on this education and experience, I am uniquely qualified and experienced as an expert in synthetic sling and mesh related issues and complications and can provide absolute standard of care testimony on all clinical aspects of this subject matter.

II. SUMMARY OF OPINIONS

In formulating my opinions and preparing this report, I reviewed scientific literature, internal documents from Ethicon, sample products, Jennifer Ramirez's deposition transcript and medical records, and depositions of Ethicon employees, among other materials. I have also

reviewed internal Ethicon documents including, but not limited to, a powerpoint and issue reports relating to the batch of mesh that was ultimately used in Jennifer Ramirez's implant and depositions of Ethicon employees. A list of all the documents reviewed for this report is attached hereto as Exhibit "B". All opinions I have are to a reasonable degree of medical and scientific certainty. In forming these opinions a broad differential diagnosis was reviewed and considered including Ms. Ramirez's medical history and conditions. I am aware discovery is still ongoing in this case, and reserve my right to amend my opinion if further information is provided in any form including, but not limited to internal Ethicon documents, depositions, new medical records, and expert reports of both Plaintiff and Defense experts. I have also reviewed and incorporate the opinions of Dr. Bruce Rosenzweig, Dr. Erin Carey and Dr. Vladimir Iakovlev herein. Specifically, I reviewed the general and case specific reports of fellow pelvic floor surgeon Dr. Rosenzweig, as well as the materials relied upon in support of those opinions, and incorporate the opinions contained in those reports, such as the numerous design defects related to the TVT-O mesh, herein. Additionally, I reserve the right to amend my opinions based on a physical examination I intend to have with the patient. In general, my expert opinions can be summarized as follows:

A. The old-construction heavyweight TVT-O mechanically cut mesh has more risks than those associated with the TVT-O laser cut mesh. Ms. Ramirez was implanted with a mechanically cut mesh TVT-O.
B. The TVT-O mesh implanted in Ms. Ramirez came from a defective lot batch which caused particle loss thereby injuring Ms. Ramirez.
C. The TVT-O IFU was incomplete and inaccurate
    a. Complications experienced by women, including Jennifer Ramirez, were not disclosed to the doctors or patients by Ethicon
    b. TVT-O IFU, Patient Brochure, or any publicly available information supplied by Ethicon does not include any language regarding mechanical or laser cut mesh nor the difference in efficacy, safety, or physician concerns and criticisms of mechanically cut mesh
    c. Ethicon Did not Study or Inform Physicians or Patients About MSDS Cancer Risks or Cytotoxicity of Mesh
D. The TVT-O caused Mrs. Ramirez's injuries which include:
    a. Dyspareunia
    b. Frequent urinary tract infections
    c. Left obturator nerve damage
    d. Depression/anxiety
    e. Chronic, long term and life altering pelvic pain
E. Mrs. Ramirez's injuries will continue to increase in number and severity

III. SCOPE OF THE PROBLEM

The average age of menopause in US women is 50 years and the life expectancy is 80 years. Thus, women live more than one third of their lives in the postmenopausal years. US Census data from 2006 show that of the 300 million US citizens on half were women, 16 million of whom were women age of 45 and older. Between 1995 and 2020, the Census Bureau predicts an increase in the number of women 45 years old and over of more than 25 million. Since the

majority of incontinence and prolapse occurs in the late and post-reproductive age group, pelvic floor defect and incontinence will continue to affect a large number of women now and well into the future. This population provides an attractive target for marketing campaigns be device manufacturers seeking to capture a high market share for devices used in the treatment of these conditions (Wall, Am. J of Obstetrics and Gynecology Jan 2010; 202.30e1-4; The Perils of Commercially Driven Surgical Innovation).

On October 20, 2008, the FDA issued a Public Health Notification that described over a thousand adverse events that had been reported over a three year period relating to the polypropylene pelvic mesh products and other similar products. Less than three years later, after the date of Jennifer Ramirez's implant, the FDA issued another Public Health Notification. This notification, directed to both pelvic organ prolapse and stress urinary incontinence implanters, described the elevated concern over these products as the number of adverse event reports had nearly tripled in a two-year period from the 2008 public health notification rising from a little over a 1,000 to 2,874 new adverse event reports.

On January 3, 2014, the American Urogynecologic Society ("AUGS") and the Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction ("SUFU") issued their Position Statement on Mesh Midurethral Slings for Stress Urinary Incontinence. This statement, created for the purpose of aiding doctors facing lawsuits based on the implantation of defective mesh, has become the crutch that manufactures, such as Ethicon, are relying on to continue selling these products and defend their products at trial. Interestingly, the doctors who authored this position statement have strong ties to the manufacturers of these products. In particular, Charles Nager, M.D., the head of the task force which authored this statement, has been a speaker and preceptor in training for Ethicon since the early 2000s, receiving payment and travel reimbursements for his support of Ethicon's mesh products.

Recently, the Scottish Cabinet Secretary for Health officially requested that pelvic organ prolapse mesh and TVT procedures be immediately suspended in their country pending further review.

IV. HISTORY OF INCONTINENCE REPAIR

Almost 200 procedures have been described in the literature for the treatment of stress incontinence alone. These procedures can be broken down into seven major categories including:

1) Anterior repair
2) Needle suspension procedures
3) Retropubic urethropexy-Open vs. Scope
4) Sling Operations- Traditional vs. New
5) Perry Urethral Injections
6) Artificial Sphincter
7) Urinary Diversion

The first sling procedure for SUI was described in 1907. This procedure, later called the Goebell-Frankenheim-Stoeckel procedure utilized the patient's own ligaments to support the return. Its only indication was for type III stress incontinence which is also known as intrinsic sphincter deficiency (ISD). ISD is characterized by an absence of urethral hypermobility, low urethral pressures and is typically seen in patients with a history of previous urethral surgery. By definition, synthetic slings are obstructive procedures which are always done blindly, thus increasing the risk of injury to adjacent organs.

In the last 15 years, synthetic sling usage has changed dramatically. Indications for synthetic sling procedures became liberalized due to several factors:

1) The increased number of baby boomers reaching menopause with stress incontinence
2) Easy to obtain cheap synthetic materials made readily available to manufacturers
3) Insurance companies push for more outpatient procedures over inpatient procedures
4) Slings are easy to teach and considered to be easy to perform
5) Slings pay more to physicians than the more time-consuming Burch procedure
6) Mesh manufacturers have marketed the products to surgeons without sufficient knowledge, training or experience

VI. THE RISKS OF THE MECHANICALLY CUT TVT-O MESH SURPASS THE RISKS OF THE LASER CUT TVT-O MESH.

In April, 2006 Ethicon produced a Clinical Expert Report on Laser Cut Mesh for the TVT (ETH.MESH.00167107). In this document, the need for switching from mechanically cut mesh (MCM) to laser cut mesh (LCM) was described as arising in response to customer needs. In particular, customers expressed a desire for a TVT mesh with smoother edges. As well, customers also expressed dissatisfaction with the potential fraying effect of MCM.

Preclinical analysis was done showing that MCM lost approximately twice the number of particles as the LCM. This was deemed as an advantage of the LCM regarding the need to create a device with less particle loss. Interpretation of the preclinical studies concluded that "the decreased particle loss will lead to less non-functioning material left in the tissues".

An internal Powerpoint project titled "LCM Project" compared photographs of LCM to MCM pulled to 50% elongation. Results confirmed that MCM showed degradation of the structure of the mesh in certain areas where, because of particle loss, the knit had opened and a portion of the construction had been lost. Findings further concluded that, "The area may also be stretched and narrowed resulting in roping due to this occurrence". The LCM samples showed no degradation of the structure of the mesh, because no or nearly no particles had been lost. The knit construction remained intact and roping did not occur. Summary of this project concluded that the LCM resists degradation of the knit construction, particle loss and permanent narrowing better than the MCM. LCM samples proved more consistent in their good results.

An internal e-mail chain dated November 21, 2005 (ETH.MESH.00301741) discussed the known advantage of LCM over MCM. Christophe Vail states in his e-mail specifically, "Particle loss is the reason why TVT wants to use laser cut mesh, to eliminate particle loss (which is critical to quality). Laser cut is a very good improvement since it probably does not significantly impact the other CTQs (elongation curve and flexural rigidity)."

In his deposition dated 6/12/13 page 213-4, Gene Kammerer concurred that the device

functionality, was improved by incorporating the laser cut mesh. Specific advantages mentioned were, a decrease of the mesh construction degradation (fraying), a decrease in particulate loss, and a reduction of roping or permanent narrowing of the mesh as it is stretched.

VII. THE TVT-O MESH IMPLANTED IN MS. RAMIREZ CAME FROM A DEFECTIVE LOT BATCH WHICH CAUSED PARTICLE LOSS.

Particle loss occurs when the TVT-O polypropylene mesh is stretched causing the outer material to flake off. As stated above when the mesh is mechanically cut, the risk of particle loss increases. Particles loss can occur in several places including, but not limited to, when the mesh is cut, when the sheath is removed, and when the mesh is implanted. Ethicon knew about particle loss starting in 2000 but assured doctors that the effects were not clinically significant. However, particle loss is clinically significant and caused or substantially caused Ms. Ramirez's injuries.

Jennifer Ramirez was implanted with a TVT-O bearing the lot number 3405428. Prior to the date of her implant, September 2010, Ethicon started receiving complaints about that particular batch of mesh. In an internal Powerpoint created to discuss the particle loss in this batch, Ethicon reviewed pictures from complaint investigation and determined that it was acceptable. However, Ethicon protocol at that time stated that mesh particles must be smaller than 0.8 mm and there must be fewer than 5 particles per blister pack. The Powerpoint shows pictures of more than 5 particles thus showing they violated their own protocols. As a result, to a reasonable degree of medical certainty, the particle loss from this defective batch was a substantial factor in causing Ms. Ramirez's injuries.

VIII. THE TVT-O IFU WAS INCOMPLETE AND INACCURATE.

The TVT-O Instructions for Use ("IFU") in place at the time of Ms. Ramirez's implant in September, 2010 did not disclose numerous risks associated with the TVT-O even though J&J/Ethicon was aware of these risks according to Dr. Martin Weisberg (ETH.MESH.03715571, Depo 8/9/13 968:12-972:21), Janice Burns (ETH.MESH.03715571), Piet Hinoul, Dr. David Robinson, Meng Chen (ETH.MESH.04093125), and Dr. Axel Arnaud (ETH.MESH.03910175). In fact at the time the TVT-O was launched, Ethicon was aware of all the risks associated with the product that it is aware of at present day. Additionally, there is no information regarding whether the product the doctor is using is made from mechanical cut mesh or laser cut mesh. Because Ethicon knew of these risks, they should have been put in the IFU so Ms. Ramirez was informed about the risks. The risks include the following as it pertains to Ms. Ramirez's informed consent:

1. That the TVT-O is capable of causing chronic, permanent, debilitating pain, including but not limited to, obturator nerve pain;
2. The TVT-O could cause lifelong risk of erosion;
3. That erosions can be severe, untreatable and incurable;
4. Tension on the mesh could collapse the pores;

5. The complications from TVT-O could cause the patient to need lifelong surgeries to treat mesh erosions and degradation;
6. That serious and chronic inflammation could occur with the use of TVT-O and that this complication was not slight or transient;
7. That TVT-O was capable of causing permanent dyspareunia;
8. That the mesh pores could collapse under strain and cause unwanted fibrotic bridging, which was capable of causing painful scarring;
9. That the polypropylene mesh was capable of degrading;
10. That the TVT-O mesh was cytotoxic;
11. That the use of TVT-O could cause toxic shock syndrome;
12. That the TVT-O can cause de novo urinary tract infections;
13. That particle loss was a known problem and that it contributed to further unwanted foreign body reaction;
14. That Ethicon possessed evidence that the risk of vaginal scarring was greater than disclosed in its IFU;
15. The frequency, duration and severity of the risks;
16. That use of TVT-O could cause narrowing of the vaginal wall; and/or
17. That Ethicon did not have any procedure or Professional Education program to teach doctors how to properly remove TVT-O mesh slings when known complications occurred;
18. That manufacturers of polypropylene resin stated that it should not be used in the human body;
19. That the polypropylene resin used for the mesh in the TVT-O induced sarcomas at the site of implantation.
20. That TVT-O complications are in many cases permanent, severe and irreversible.

Ms. Ramirez did not receive information about the above risks because Ethicon did not disclose them in its IFU. This is true despite the information available to Ethicon about these risks since the launch of the product. As such, Ms. Ramirez was unable to make a fully informed decision about having the TVT-O implanted. As a result, to a reasonable degree of medical certainty, Ms. Ramirez suffered injuries that were not disclosed to her by Ethicon or her physician (based on Ms. Ramirez's deposition testimony) and the inadequate disclosure of these risks were a substantial factor and/or in causing Ms. Ramirez's injuries.

IV. THE TVT-O CAUSED MRS. RAMIREZ'S INJURIES AND WILL CONTINUE TO CAUSE FUTURE INJURIES

I was asked to review the pertinent medical records of Ms. Jennifer Ramirez and to provide in this report my opinions of her care and treatment as well as a probable prognosis. Mrs. Ramirez's injuries result from the implantation of the mesh and the defects of the mesh itself which include, but are not limited to, roping, fraying, curling, degradation, shrinkage, contraction, and particle loss, especially when in close proximity to the obturator nerve bundle and muscles, which are evidenced by the chronic inflammation, scarring, and fibrosis seen in her Zimmern explant operative and pathology reports.

Pertinent Surgical/Medical history:

- Laparoscopy for endometriosis
- Three vaginal deliveries
- Laparoscopic tubal ligation-no endometriosis seen
- 9/17/10-Total laparoscopic hysterectomy with TVT-O for menorrhagia, fibroids, dysmenorrhea and SUI. Findings included fibroids and adenomyosis without endometriosis
- 9/27/10-Postoperative visit, UTI treated with Macrobid
- 10/08/10-Phone Note, patient c/o urinary pain and frequency after Macrobid, Levaquin called in
- 11/14/10-Phone Note, patient c/o recurring UTI's since surgery
- 11/15/10-Office visit with Urologist Dr. Talley. Complains that since sling surgery 2 months she's had:
    - weak stream, hesitancy, difficulty maintaining stream, intermittency, incomplete bladder emptying, dysuria, urgency, frequency, 2 UTI's since sling and pain with voiding
  - Physical Exam showed:
    - Vagina with "bowstringing" of tape on left side of urethra without erosion
    - Cystoscopy normal
  - Assessment:
    - Pelvic pain after BN sling. Feel is bowstring of sling
  - Plan:
    - Valium to relax pelvic muscles. Return so see Dr. Graham to discuss possible incision of BN sling
- 11/23/10-Office visit with Urologist Dr. Graham c/o voiding difficulty, vaginal bleeding after sex or bowel movement and painful left side with sex
  - Physical Exam showed:
    - Palpable mesh deep to vaginal wall left side urethral. Entire left side pelvic floor tender with trigger point at the insertion
  - Assessment:
    - Dyspareunia-mesh arm tight left side
  - Plan:
    - Discussed cutting sling or physical therapy. Try valium before sex. Pelvic floor therapy to release left side levator at sling insertion site. Return visit in 4 weeks
- 12/01/10-Office visit with Nurse Practitioner c/o vaginal discharge for 6 days, vaginal bleeding for 3 weeks and just completed Macobid 2 days ago
  - Physical Exam showed:
    - Scant pink discharge. Tender in left inner vaginal wall, "where mesh was placed" and vaginal cuff with granulation tissue (treated with silver nitrate)
- 12/02/10-Emergency Room visit for increased vaginal bleeding from granulation tissue treated with silver nitrate
- 12/06/10-Follow up with Urologist Dr. Graham.
  - Assessment:

        - Pelvic pain. Tight left insertion of TOT. Vaginal bleeding
    - Plan:
        - Vaginal exploration and revision of sling
- 12/22/10-Surgery, Dr. Graham. Partial excision of TOT and excision/fulgeration of granulation tissue at cuff
    - Preoperative/Postoperative diagnosis: Pelvic pain from TOT
    - Indications for surgery:
        - Appears to have pain in the left side of her pelvis with a trigger point at the insertion site of her TOT
    - Procedure:
        - Dr. Graham felt left side of TOT mesh at insertion into the obturator muscle after which he excised approximately 1cm portion of the mesh
- 5/02/11-Office visit Sudhir Gogu PhD for depression after separation from husband. Denied another significant event. Treated with antidepressant
- 8/30/11- office visit with Dr. Graham c/o urinary urge incontinence beginning after excision/revision of TOT.
    - Physical Exam showed:
        - Urethra was hypermobile and unable to pass Q-tip, tender levator left side bladder neck
    - Summary of findings:
        - Urge incontinence began after excision of TOT
    - Plan:
        - Pelvic floor therapy
- 9/13/11-Gyn office visit requests STD screen (spouse unfaithful). Results, positive HSV1
- 5/24/12-Gyn office visit annual exam and screen for STD. Positive Chlamydia, given Zithromax
- 7/03/12-Gyn office visit. STD screen negative
- 4/9/13-Gyn office visit. Reported dyspareunia occurring with deep thrust and indicated this has been a problem for two years.
- 5/7/13-Family Care office visit. Follow up for anxiety and depression, counseling and Celexa
- 6/23/14-Ramirez deposition. Constant pelvic pain radiating down left leg with numbness since around 2011 (starting page 97 of depo). Page 269, saw Dr. Atkerson complaining of dyspareunia. Page 272 complains of pain with anything inserted into vagina. Page 274 c/o urinary frequency.
- 11/21/14- Office visit with Urologist Dr. Kathleen Chin as a new patient for Dr. Phillipe Zimmern. Constant pain, level six, in lower left abdominal region.
    - Physical Exam showed:
        - pain in the lower left quadrant, down medial, upper aspect of left thight; left sided vaginal discomfort with gentle palpation in trajectory of mesh tape
    - Plan:
        - Future appointment with Dr. Zimmern to discuss possibility of surgery.
- 1/22/15-Office visit with Dr. Phillipe Zimmern.
    - Physical exam showed: chronic trigonitis and very tight distal urethra.

  - Plan: removal surgery, scheduled for March 10, 2015
- 3/9/15-Pre-op visit. Reported history of chronic pain in pelvic area for four years. Since revision she has had frequency and urgency incontinence, a constant pain and pain shooting down left leg, frequent UTIs, bacterial infections, and dyspareunia.
  - Physical Exam showed: pain on inner side of the left thigh, pain inside vagina on left side, tenderness along course of mesh tape, and extensive trigonitis.
  - Plan: surgery to remove mesh along the left side.
- 3/10/15-Surgery, Dr. Zimmern. Removal of transobturator tape remnant, cystoscopy
  - Preoperative/Postoperative diagnosis: dyspareunia, dysuria, and incomplete bladder emptying
  - Indications for surgery: She presented with tenderness in the distal urethra, voiding dysfunction and dyspareunia
  - Procedure: Cystoscopy was first performed. Urethra appeared very narrow and compressed. Grade 4 trabeculations were noted as well as squamous metaplasia. The blue weaves of the mesh were identified below the vaginal surface on the left side of the urethra. The edges were grasped and lifted off the floor of the urethra from left to right. The tape was removed completely all the way until it disappeared behind the pubic arch. The left side was then explored in a similar fashion. Palpation through the obturator internus was done and no further tape remnant was noted. Cystoscopy was performed again showing a normal urethra with no distortion.
- 3/11/15- Pathology Report: two fragments of blue, flexible mesh embedded with friable to partially cauterized soft tissue. Final diagnosis: synthetic mesh material embedded with fibrous tissues with chronic inflammation.

Opinions and Conclusion

Based on my review of the records, my education and experience, and review of pertinent literature, I hold the following opinions to a reasonable degree of medical certainty:

1. Jennifer Ramirez developed numerous complications set forth above as a result of the TVT-O device being implanted into her body, which currently include:
   a. Dyspareunia resulting from the scarring and fibrosis on the Zimmern operative and pathology reports, the chronic inflammation due to the defects of the mesh which include the roping, fraying, curling, and degradation, as well as rigidity of the mesh.
   b. Frequent urinary tract infections resulting from the partial bladder outlet obstruction the sling was causing which is documented in the Zimmern operative report
   c. Left obturator nerve damage causing left side groin, leg, and vaginal pain resulting from the scarring pulling on the nerves and the chronic inflammation discussed above causing irritation
   d. Pelvic pain resulting from the scarring, the inflammation discussed above, and rigidity of the sling and their effects on all adjacent tissue
2. As a result of the complications from the TVT-O device, Jennifer Ramirez has suffered damages and will continue to suffer damages

3. I have reviewed Jennifer Ramirez's medical bills related to her treatment and surgeries related to her complications from the TVT-O and believe they are customary, reasonable and necessary.

4. At the age of 40, there is a reasonable probability that she will be disabled and unable to work.

I reserve the right to supplement my opinion regarding her injuries and reasonable necessity of future care as her prognosis develops.

VIII. EXHIBITS

My current curriculum vitae is attached here to as Exhibit "A"

All exhibits that will be used to support my findings and opinions or documents that I have reviewed are referred to herein are listed in Exhibit "B"

XII. RECENT TESTIMONY

In the previous four years, I have testified, by deposition or in trial, in the following cases:

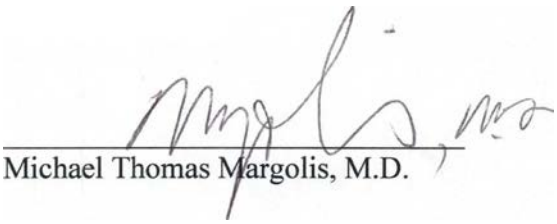
- Coleen Perry v. Luu, et al.
- Martha Salazar v. Lopez, et al.
- Linda Batiste v. Johnson & Johnson and Ethicon, Inc.
- Elizabeth Ayerdis v. Hawaii Permanente Medical Group
- Carpenter v. Hardesty, et al; Superior Court of the State of California, San Bernadino County
- Sabrina Gaines v. Kendal Freeman, et al.
- Gross v. Gynecare, New Jersey Superior Court, Atlantic County Division
- Harrison v. Eberts
- Lorie Koop v. George Stankevych
- Tracey Patane v. Ardent Health Services, et al.
- Pamela Russell v. Neil Harrison, et al.
- Rizzo, et al. v. C.R. Bard, Inc., United Stated District Court, Northern District of Georgia
- Scorpio v. Noone
- Waddoups v. Barry Noorda, et al., United States District Court, District of Utah

IX. COMPENSATION

My time is billed as follows: $350 per hour for review and preparation; $500 for deposition testimony; $2,000 per day for trial appearance.

I declare under penalty of perjury that the foregoing is true and correct.

This the 24th day of April, 2015.



Michael Thomas Margolis, M.D.